

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL NO. 1456
LITIGATION)	
)	ACTION: 01-CV-12257-PBS
)	
THIS DOCUMENT RELATES TO:)	JUDGE PATTI B. SARIS
)	
THE MASTER CONSOLIDATED)	CHIEF MAGISTRATE JUDGE
CLASS ACTION)	MARIANNE B. BOWLER
)	

**MEMORANDUM OF BOEHRINGER INGELHEIM CORPORATION, BEN VENUE
LABORATORIES INC., AND BEDFORD LABORATORIES IN OPPOSITION TO
PLAINTIFFS' MOTION TO SUBSTITUTE PARTY**

I. INTRODUCTION

On April 7, 2004, Boehringer Ingelheim Corporation ("BIC"), Ben Venue Laboratories, Inc. ("Ben Venue") and Bedford Laboratories ("Bedford") (collectively "Defendants")¹ filed a motion to dismiss on the grounds that the allegations in Plaintiffs' Amended Master Consolidated Class Action Complaint ("AMCC")² contain fatal jurisdictional and substantive defects. Instead of filing a response grounded in the AMCC alone, on April 27, counsel for Plaintiffs (and the proposed intervenor) took the extraordinary step of filing both this motion to amend the AMCC to substitute parties, and a companion motion to intervene in an effort to salvage the claims against the Defendants. Counsel's maneuver all but concedes Defendants' point -- that the AMCC, now in its fifth version, is **still** insufficient to keep BIC, Ben Venue, and Bedford as defendants in the class action. Defendants' Motion to Dismiss must therefore be granted.

¹ BIC, Ben Venue and Bedford use this nomenclature solely for the convenience of this Court and deny that Plaintiffs' designation of them as a group is accurate or appropriate.

² As amended on December 5, 2003 and January 22, 2004.

In addition, under both Rules 15 and 21 of the Federal Rules of Civil Procedure, this Court should deny Plaintiffs' motion to amend the complaint to substitute a party. First, substitution of Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") for BIC does nothing to cure the fatal jurisdictional defect in Plaintiffs' AMCC, and so would be a futile act. Second, Plaintiffs have not offered any excuse for their delay, and have not demonstrated that amendment now would not prejudice the existing defendants. Third, Plaintiffs have not demonstrated that they have notified BIPI within the time allowed by Rule 15 (c) or that there was any reason, other than conscious choice, or inexcusable neglect, for declining to name BIPI as a defendant despite three years and four amendments to the AMCC.

Plaintiffs' policy throughout this litigation has been to level serious accusations at the defendants, as quickly as possible, with little to no factual basis, in the hope that any deficiencies in their case may be remedied by what has been an endless cycle of amendments and interventions. It is time for this merry-go-round to stop, for Plaintiffs to take responsibility for their allegations, and to have their case resolved on the pleadings currently before this Court.

The Motion to Substitute should be denied.

II. STANDARD OF REVIEW

"While leave to amend shall be freely given when justice so requires . . . the liberal amendment policy prescribed by Rule 15(a) does not mean that leave will be granted in all cases." *Acosta-Mestre v. Hilton Int'l of P.R., Inc.*, 156 F.3d 49, 51 (1st Cir.1998). Among the reasons to deny a motion to amend are: "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue

prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment.” *Fomen v. Davis*, 371 U.S. 178 (1962) (emphasis added).

Further, “when considerable time has elapsed between the filing of the complaint and the motion to amend, the movant has the burden of showing some valid reason for his neglect and delay.” *Acosta-Mestre*, 156 F.3d at 52 (quoting *Stepanischen v. Merchs. Despatch Transp. Corp.*, 722 F.2d 922, 933 (1st Cir. 1983)). And, where the motion to amend comes after responsive pleadings have been served, as in this case, the standard for adding a party is the same whether the motion is made under Rule 15 or Rule 21, because in both cases the moving party must demonstrate an absence of prejudice to the nonmoving party. *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 825 F.Supp. 340, 344 (D. Mass. 1993).

Considering these factors, Plaintiffs have utterly failed to demonstrate that, after three years and five complaints, they should be granted leave to file yet a sixth complaint in this action.

III. ARGUMENT

A. Defendants promptly and properly challenged the subject matter jurisdiction of the court due to Plaintiffs’ failure to properly allege a purchaser of any drug manufactured or distributed by Defendants

Defendants timely challenged Plaintiffs’ amendment of the AMCC to include Atrovent. On December 19, 2001, Plaintiffs filed their first complaint, which did not name BIC, Ben Venue, or Bedford. On or about September 10, 2002, Plaintiffs served a Master Consolidated Class Action Complaint (“MCC”), which for the first time named BIC, Ben Venue, and Bedford as members of a so-called “Boehringer Group.” See MCC ¶¶ 75-78. On June 12, 2003, in direct response to this Court’s Order of May 13, 2003, Plaintiffs filed their first AMCC, which included an Appendix A that Plaintiffs alleged contained “each of the specific drugs that are the subject of

the claims herein” (*see* June 12 AMCC ¶ 11, at App. A) as well as each drug’s allegedly fraudulent average wholesale price (“AWPs”), and an Appendix B that identified each of the plaintiffs who purchased the drugs in Appendix A for purposes of standing. *See* June 12 AMCC ¶ 11. Atrovent was listed nowhere in either Appendix A or Appendix B.

On November 21, 2003 this Court heard oral argument on motions to dismiss the June 12 AMCC; during that hearing the Court granted Plaintiffs leave to amend. They did so, and served an amended AMCC on December 5, 2003. Calling their prior omission “inadvertent[],”³ Plaintiffs added Atrovent to Appendix B in this December AMCC as a drug for which a purchaser was alleged, but still did not list Atrovent in Appendix A as “subject of the claims herein” nor allege a fraudulent AWP for this drug. *Compare* Dec. 5 AMCC, App. B, *with* Dec. 5 AMCC, App. A. On January 22, 2004, Plaintiffs filed yet another amended AMCC (by way of intervention of individual plaintiffs), but still did not list Atrovent in Appendix A as drugs that are “subject of the claims herein” nor allege a fraudulent AWP for this drug.

Plaintiffs did not list Atrovent in Appendix B of the AMCC as a drug for which a plaintiff claims standing to sue until the December 5, 2003, and even then did not allege Atrovent in Appendix A as a drug “subject of the claims herein.” Plaintiffs served the December 5 AMCC on Defendants while this Court still had a motion to dismiss the June 12 AMCC pending before it, and which, if granted, would have obviated the need to brief the Court on specific-defendant matters raised in the December 5 AMCC.

Moreover, BIC, Ben Venue and Bedford had **no reason to believe** that Atrovent was part of this case, since Plaintiffs have never listed Atrovent on Appendix A, have never identified a fraudulent AWP for Atrovent, and still have not alleged a fraudulent AWP for Atrovent.

³ Pls.’ Notice of Filing of AMCC Modified Per the Court’s Instruction at the Nov. 21, 2003 Hearing, at ¶ 3

Shortly after it became clear that Plaintiffs believed that their allegations with respect to Atrovent kept Defendants' in the case (which was manifested by Plaintiffs' March 31, 2004 service of discovery, Defendants filed their Motion to Dismiss stating that they were not proper parties. (In fact, each time the Defendants have had the opportunity, they have stated they are not proper parties.)⁴ Therefore, it is disingenuous for Plaintiffs to argue that Defendants waited too long to challenge Plaintiffs' standing to sue BIC as a defendant in connection with Atrovent.⁵

Moreover, as is well-established, challenges to the subject matter jurisdiction of a federal court can be made at any time. *See Halleran v. Hoffman*, 966 F.2d 45, 47 (1st Cir.1992) ("A challenge to federal subject matter jurisdiction may be raised at any time, including for the first time on appeal."); *see also* Fed.R.Civ.P. 12(h)(3) ("Whenever it appears . . . that the court lacks jurisdiction of the subject matter, the court shall dismiss the action."). Defendants challenged the subject matter jurisdiction of this Court because the AMCC by its own terms does not contain any claim that any plaintiff purchased a drug that is subject of any allegations in the complaint. As there is no proper allegation of purchase of any Defendants' drug in this case, there is no allegation of injury fairly traceable to any act of Defendants, and jurisdiction is improper.

Defendants' challenge is entirely appropriate.

⁴ For instance, before Atrovent had been mentioned, but when Viramune had been mentioned, Defendants moved to dismiss on the ground that neither BIC, Ben Venue nor Bedford manufactured Viramune. *See* Mem. of the Boehringer Defendants to Pls.' Separate Mem. In Opp. to Defendant-Specific Memoranda On Mot. to Dismiss. And since Plaintiffs continue to change their "theories," the reasons the various defendants are not proper parties have changed.

⁵ Specifically, Plaintiffs argue, at p. 2 of their Motion to Substitute, "Despite ample opportunity to previously advise the Court during briefing on the motions to dismiss that BIC is the wrong party, the Boehringer Defendants failed to do so. Instead, now for the first time, the Boehringer Defendants claim that BIC does not manufacture or distribute Atrovent."

B. Adding BIPI at this stage of the litigation would be futile, prejudicial and unjust

1. This Court should deny the motion to substitute because Atrovent – the alleged reason for the substitution – is not one “of the specific drugs that are the subject of the claims” in the AMCC, does not have an allegedly fraudulent AWP associated with it, and so amendment is a futile act.⁶

Plaintiffs are attempting to substitute one defendant for another on a drug which, by the Plaintiffs’ own complaint, is not “subject of the allegations” in this suit and for which there is no allegation of a fraudulent AWP. Hence, this substitution would be futile and should not be permitted.

Plaintiffs argue that BIPI is a proper party defendant, because BIPI produces Atrovent. However, by the terms of Plaintiffs own complaint Atrovent is not a drug at issue in this case. As Defendants stated in their April 7, 2004 Motion to Dismiss, “Atrovent appears nowhere in Appendix A to the AMCC as a drug ‘subject of the claims herein.’ Consequently, Atrovent must be dismissed”⁷ Plaintiffs asserted unequivocally in paragraph 11 of the December 5, 2003 AMCC and in paragraph 11 of the June 12, 2003 AMCC that Appendix A is “a list of each of the specific drugs that are the subject of the claims herein.” **This admission in paragraph 11 binds Plaintiffs.** See *Schott Motorcycle Supply, Inc. v. Am. Honda Motor Co., Inc.*, 976 F.2d 58, 61 (1st Cir. 1992) (“[A]dmissions in the pleadings are binding on the parties ...”);⁸ *Official Comm. of Unsecured Creditors of Color Tile, Inc. v. Coopers & Lybrand, LLP*, 322 F.3d 147 (2d Cir. 2003) (“the allegations in the Second Amended Complaint are ‘judicial admission[s]’ by which

⁶ Although BIC believes it should be dismissed from the AMCC, BIC believes that dismissal should occur by this Court granting the Defendants’ Motion to Dismiss and that the Motion to Substitute of plaintiffs is an unwarranted attempt to have the Court disregard the Motion to Dismiss.

⁷ Motion to Dismiss (Apr. 7, 2004), at 5 (emphasis in original).

⁸ Quoting *Missouri Housing Development Commission v. Brice*, 919 F.2d 1306, 1315 (8th Cir. 1990).

Color Tile Committee was ‘bound throughout the course of the proceeding.’”)⁹ **Atrovent, therefore, is not part of this case.**

Plaintiffs do not -- and cannot -- dispute Defendants’ jurisdictional grounds to dismiss BIC, Ben Venue, and Bedford from the AMCC. This Court clearly instructed Plaintiffs in its May 13, 2003 Order that for each defendant Plaintiffs must specify a purchaser, the manufacturer of the drug purchased, and a purported fraudulent AWP. *See* Mem. and Order (May 13, 2003), at 45. Plaintiffs are “master of their own complaint” and their own complaint states that Appendix A is the definitive list of drugs and fraudulent AWP’s for which relief is sought, *see* AMCC ¶ 11, and their own complaint states that Appendix B lists which Plaintiff purchased which drug. *See, e.g.*, AMCC ¶ 27 (“All drugs covered by this Complaint purchased by this plaintiff are identified in Appendix B.”), ¶ 28 (“The drugs purchased by TCBW at issue in this litigation are identified in Appendix B.”), ¶ 31 (“All of Man-U Service Fund’s drugs at issue in the Complaint are identified in Appendix B.”). It is therefore wholly offensive for Plaintiffs to call Defendants’ Motion to Dismiss “disingenuous[.]”¹⁰ when, by the terms of Plaintiffs’ own complaint, the only drug that Plaintiffs claim was purchased by any plaintiff is a drug not even subject to the claims in this litigation and for which there is no alleged AWP.

Since Atrovent is not and has never been part of this case, per the binding admission of paragraph 11 of the AMCC, and since there is no source for an allegedly fraudulent AWP anywhere in the AMCC, substituting a company that produces Atrovent would not give this Court subject matter jurisdiction over this case. As the court held in *Lans v. Gateway 2000, Inc.*, 84 F.Supp.2d 112, (D.D.C. 1999), “when a plaintiff never had standing to assert a claim against

⁹ Quoting in part *Bellefonte Re Ins. Co. v. Argonaut Ins. Co.*, 757 F.2d 523, 528 (2d Cir. 1985).

¹⁰ *See* Mot. to Substitute, at 1.

the defendant, **plaintiff may not substitute a new plaintiff, a new defendant, or a new claim for the purpose of creating jurisdiction.**” *Id.* at 116 (emphasis added).

When an amendment would be futile because it would not correct the deficiencies in a complaint, a court should deny the amendment. *See Hatch v. Dept. for Children, Youth & Families*, 274 F.3d 12, 19 (1st Cir. 2001); *Taylor v. F.D.I.C.*, 132 F.3d 753, 766, n. 7 (D.C.Cir. 1997) (quoting *Correa-Martinez v. Arrillaga-Belendez*, 903 F.2d 49, 59 (1st Cir. 1990)); *see also Maine State Bldg. & Trades Council v. U.S. Dep’t of Labor*, 359 F.3d 14, 19 (1st Cir. 2004). Atrovent simply is not one “of the specific drugs that are the subject of the claims herein.” Even if Plaintiffs substituted BIPI for BIC, they still have not alleged Atrovent as part of this case, and have not alleged a fraudulent AWP for that drug. As substitution of the manufacturer of Atrovent would be a futile act, this Court should deny the Motion to Substitute.

Finally, even if this Court were decide to substitute BIPI for BIC, **and** to allow Plaintiffs to amend the Complaint to fix Appendix A, **and** to allow Plaintiffs to amend to add a fraudulent AWP, **and** have the amendment relate back to some indeterminate point in the past (since BIC was not named in the original complaint), even then, the standing problem with respect to Ben Venue and Bedford is not corrected, because there is no allegation in Appendix B that any purchaser has purchased any of their drugs. Consequently, even if a sixth complaint were permitted, Ben Venue and Bedford should still be dismissed from this suit.

2. Plaintiffs have offered no explanation why they did not name BIPI despite at least five opportunities to do so over the past three years

Where a considerable period of time has passed between the filing of the complaint and the motion to amend, the movant must show some valid reason for his neglect and delay. *Hayes v. New England Millwork Distribs., Inc.*, 602 F.2d 15, 19-20 (1st Cir. 1979); *Tingley Sys. Inc. v. CSC Consulting, Inc.*, 152 F.Supp.2d 95, 116 (D. Mass. 2001). Plaintiffs have offered no reason

whatsoever why they did not name BIPI in this suit despite five complaints over the past three years. Indeed, their actions can only be ascribed to either to a conscious strategic decision, or (as is more likely) to a consistent pattern of disregard for this Court's instructions and inexcusable negligence.

More than four months ago, in allowing a different amendment to the AMCC, the Court admonished Plaintiffs that its patience was running thin. It cautioned that the next amendment would be "it" with respect to further amendments.¹¹ Plaintiffs, presumably taking this warning seriously, responded with the December 5 AMCC, which purported to correct claims that had been "inadvertently omitted" from the June 12 AMCC, and to correct other "scriviner's error[s]." Pls.' Notice of Filing of AMCC Modified Per the Court's Instruction at the Nov. 21, 2003 Hearing, at ¶ 3. Inexplicably, Plaintiffs totally failed to substitute BIPI or to add Atrovent to the list of drugs and fraudulent AWP's in Appendix A.

Plaintiffs' suggested reliance on 2002 annual report is specious. First, that report was published in 2003, months after Plaintiffs had consciously named BIC in the September MCC.¹² Furthermore, that reliance is puzzling given that the Physician's Desk Reference ("PDR"), an industry standard, and one which includes the manufacturers own identification of themselves and their drugs, was readily available. *See* PDR, at § 5, (Thompson 55th ed. 2001). At all times a cursory examination of the PDR would have revealed that BIPI and not BIC, Ben Venue, or Bedford were the manufacturers of Atrovent. *See, e.g.*, PDR 1027, 1030 (57th ed. 2003); PDR 1031, 1033 (56th ed. 2002); PDR 964, 966, 967 (55th ed. 2001). In fact, Defendants pointed Plaintiffs to this very reference in January when Defendants argued that they should not be subject to discovery on Viramune, because Viramune was not named in Appendix A and is not

¹¹ Page 119 of transcript of November 21, 2003 hearing.

¹² *See* Boehringer Ingelheim Annual Report, at 89 (showing auditors did not certify results until February 17, 2003); *id.* (showing copyright of 2003).

manufactured by any of the named Defendants. *See* Mot. for Protective Order of BIC, Ben Venue, and Bedford and Mem. in Support (filed January 5, 2004), at 6-7.

As stated by the First Circuit in *Hatch*, “undue delay . . . [or] repeated failure to cure deficiencies by amendments previously allowed . . .” both serve as valid reasons for denial of an further amendments. 274 F.3d at 19 (emphasis added); *see also Acosta-Mestre v. Hilton Intern. of Puerto Rico, Inc.*, 156 F.3d 49, 52 (1st Cir. 1998). Plaintiffs had five opportunities to name BIPI but failed to do so. They have offered no excuse for failing to name BIPI because they have no excuse. They either consciously chose to ignore BIPI or consciously chose to defy this Courts’ admonition that further amendments would be disfavored. This Court should therefore grant the Motion to Dismiss of BIC, Ben Venue and Bedford.

3. Plaintiffs have not explained how further amendment by substitution of parties is not prejudicial to the defendants in this suit

Even putting aside the fact that undue delay and repeated failures to fix pleading defects are sufficient to deny leave to amend, Plaintiffs have not shown that the non-moving parties will not be prejudiced by this substitution. As this District Court held in *Data Gen Corporation*, “[w]here the motion to amend comes after responsive pleadings have been served, . . . the **moving party must demonstrate an absence of prejudice to the nonmoving party.**” 825 F.Supp. at 344 (citations omitted)(emphasis added). This requirement applies whether the amendment is by leave under Rule 15 or Rule 21. *Id.* Here, the non-moving parties are **all the defendants**, so plaintiffs would have to show that the delays caused by the substitution of BIPI would not prejudice the other defendants. Plaintiffs have made only a conclusory attempt to establish that the defendants will not be prejudiced by this sixth version of complaint.

On the other hand, the prejudice to BIPI and the other defendants in this case is apparent. As noted above, the discovery going forward is predicated on Appendix A containing the sum

total of drugs and allegedly fraudulent AWP's in this case. Plaintiffs would have to not only substitute a party but also substantially amend the AMCC to identify the drug and the fraudulent AWP in order to have standing to sue. BIPI would have the right to file a motion to dismiss and, if that were denied, an answer. Even more fundamentally, the AMCC does not mention BIPI or any of the drugs (with the exception of Atrovent) that BIPI is purported to have manufactured or distributed. "Simple" substitution of BIPI for BIC would leave a pleading to which it would be impossible for BIPI to respond, as it would not know what are the allegations against it, and what the allegedly fraudulent AWP's were.

Moreover, as explained below, Plaintiffs have not shown that substitution of BIPI would relate back to the original complaint (in which neither BIC, Ben Venue, nor Bedford was named), raising different statute of limitation issues than presented by the other defendants. The relevant period for purchases of BIPI products would be different than for the other defendants, adding unnecessary complexity to discovery and adjudication of this already extremely complex case, and adversely affecting not only the remaining Defendants and BIPI, but also the other defendants.

C. Plaintiffs Do Not Satisfy The Requirements Of Rule 15(c) Of The Federal Rules Of Civil Procedure Permitting Relation Back

1. The proposed amendment/substitution of BIPI cannot relate back to the original complaint

Plaintiffs claim in conclusory fashion that, if allowed, the amendment should relate back to the filing of the original complaint. Plaintiffs bear the burden of demonstrating conclusively that each element of 15(c), governing relation back, is met. *See Leonard v. Parry*, 219 F.3d 25, 31 (1st Cir. 2000); *Hazleton v. City of Grand Prairie, Tex.*, 8 F.Supp.2d 570, 580 (N.D. Tex. 1998). They have not done so.

An amendment to a pleading may relate “back to the date of the original pleading,” if “(2) the claim or defense asserted in the amended pleading arose out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading.” Fed R. Civ. P. 15(c). Of course, Plaintiffs did not name any of the Defendants in the original complaint, just as the plaintiffs did not name many other pharmaceutical manufacturers in the original complaint, so subsection (2) is not applicable.

Plaintiffs rely on Rule 15(c)(3) to make their claim¹³ about “relating back,” but neglect to mention, let alone quote, the beginning requirement of Rule 15(c)(3):

the amendment changes the party or the naming of the party against whom a claim is asserted **if the foregoing provision (2) is satisfied and**, within the period provided by Rule 4(m) for service of the summons and complaint, the party to be brought in by amendment ...

(emphasis added). Since Plaintiffs did not name BIC, Ben Venue, or Bedford in the original complaint, Plaintiffs have not demonstrated that provision (2) is satisfied, thus, Plaintiffs have not shown provision (3) to have been satisfied. In other words, even if the Court granted the Motion to add BIPI as a party, the amendment adding BIPI would not relate back to the original complaint, raising new statute of limitations and related issues that further complicate this litigation for the Court and defendants.

2. BIPI would not reasonably be expected to know that Plaintiffs would name any of them as defendants

Disregard for the sake of argument, however, as Plaintiffs have done, the fact that Rule 15(c)(3) is inapplicable as a result of the first requirement of Rule 15(c). The remainder of Rule 15(c)(3) requires that Plaintiffs establish that the proposed additional defendant “knew or should

¹³ Mot. to Substitute, at 3.

have know that, but for a mistake concerning the identity of the property party, the action would have been brought against the party.”

Although Plaintiffs named a number of pharmaceutical manufacturers in the June 12, 2003 AMCC, Plaintiffs did not name numerous other manufacturers. Plaintiffs have not demonstrated that BIPI, or any other non-named defendant, had any reason to believe that its omission was a case of mistaken identity. Indeed, if Plaintiffs argue that BIPI should have known it would be named, because Plaintiffs named BIC, Ben Venue, and Bedford in the MCC, it remains an open question why Plaintiffs named none of these Defendants in the original complaint. In fact, one would assume that the MCC allegations and new parties would have been drafted with care. By Plaintiffs’ own “reasoning,” therefore, BIPI had no reason to believe after the filing of the original complaint that Plaintiffs would subsequently name BIPI years later.

In fact, Plaintiffs made a conscious choice to sue BIC, not BIPI. The MCC and the AMCC are extremely detailed about the corporate structure of BIC, its parents and subsidiaries. Paragraph 64 of the December 5, 2003 AMCC, and paragraph 64 of the June 12, 2003 AMCC, allege “defendant Boehringer Ingelheim Corporation (‘Boehringer’) is a Nevada corporation with its principal place of business located at 900 Ridgefield Road, Ridgefield, Connecticut. Boehringer is a United States subsidiary of Pharma Investment Ltd. of Burlington, Canada, which in turn is a division of CH Boehringer Sohn Gurdstücksverwaltung GmbH & Co. KG of Ingelheim Germany.” Such detail in description, even down to the corporate parent in Germany, betrays a knowledge of the corporate structure of BIC, Ben Venue, and Bedford, and belies the claim that the omission of BIPI was simply an accident. Plaintiffs were precise – and precisely wrong.

Further, as stated above, in the motions filed by the Defendants in response to the June 12 AMCC and discovery, the Defendants referred to the PDR to show that it did not manufacture Viramune. *See supra*, at p.9. The PDR expressly identifies Boehringer Ingelheim Pharmaceuticals, Inc. as the manufacturer of a variety of pharmaceutical products, **including Atrovent**. *See supra*, at p. 9. Yet in the December 5, 2003 AMCC Plaintiffs continued to sue BIC, not BIPI.

Plaintiffs may have made a mistake in judgment, but Plaintiffs did not “misname” the defendant. Thus, Rule 15(c) does not apply. For instance, in *Wilson v. U.S. Gov’t*, 23 F.3d 559 (1st Cir. 1994), the First Circuit explained:

In this case, there was no “mistake concerning the identity of the proper party,” as required by Rule 15(c)(3). Rather, Wilson merely lacked knowledge of the proper party. In other words, **Wilson fully intended to sue GEGS, he did so, and GEGS turned out to be the wrong party. We have no doubt that Rule 15(c) is not designed to remedy such mistakes.**

Id. at 562-63 (emphasis added); *see also Roman v. Townsend*, 224 F.3d 24, 28, n. 5 (1st Cir. 2000) (“The purpose of Fed.R.Civ.P. 15(c)(3) is to correct a formal defect such as a misnomer of misidentification”); *Sundel v. United States*, 67 F.3d 289, 1995 WL 597221, *2 (1st Cir.1995) (unpublished) (“Rule 15(c) ordinarily applies only when “the proper defendant is already before the court and the effect is merely to correct the name under which he is sued”).

Indeed, Plaintiffs alternatively seemed to allege that they were justified in naming BIC, and that BIPI should have known that it was the actual defendant. They can’t have it both ways. For whatever reason, Plaintiffs consciously decided to sue BIC, and continued to do that even though it was clear that BIPI manufactures pharmaceutical products and the parent corporation, BIC, does not.

III. CONCLUSION

Plaintiffs claim that after four years, BIPI should be substituted as a party defendant because of Atrovent. Yet the AMCC has never, and still does not, allege Atrovent as a drug at issue in this case, and Plaintiffs have never, and still have not, listed an alleged inflated AWP for Atrovent. As a result, adding BIPI would be a futile act. If BIPI were added as a party defendant, it should have the right (1) to be served with the pleading naming BIPI as a defendant and (2) to file a motion to dismiss to challenge the propriety of it being named as a defendant, thereby adding delays to the complex litigation, all of which would be caused by Plaintiffs having made conscious, and perhaps poorly researched, decisions in their choice of defendants. Finally, Plaintiffs have offered no support for the proposition that, even if amendment were permitted, such an amendment would relate back to the original complaint. However, since this Court does not have jurisdiction of any claims in this suit, and since Atrovent is not a drug at issue in this case, this Court should grant the Defendants' Motion to Dismiss and deny the Motion to Substitute BIPI as a party defendant for BIC.

Dated: May 11, 2004

Respectfully submitted,

/s/ Paul J. Coval [signature on file with Court]

Paul J. Coval

Douglas L. Rogers

Darrell A. H. Miller

VORYS, SATER, SEYMOUR AND PEASE LLP

52 East Gay Street

P.O. Box 1008

Columbus, Ohio 43216

(614) 464-6400

(614) 464-6350 FAX

*Attorneys for Boehringer Ingelheim Corp., Ben
Venue Laboratories, Inc./Bedford Laboratories*

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing document was served on all enrolled counsel via Verilaw on May 11, 2004 pursuant to this Court's Case Management Order 2.

/s/ Paul J. Coval [signature on file with Court]
Paul J. Coval